REMARKS

A. THE OFFICE ACTION

Claims 1, 3-9, 11-17, 19-30, 32-56, and 65-83 are pending. Claims 17, 39-56, and 65-83 are withdrawn from consideration, claims 19-29 are allowed, and claims 1, 3-9, 11-16, 30, and 32-38 are currently under examination insofar as the claims read on a composition or a preparation comprising an antibody that binds to a peptide of NF-κB inducing kinase (NIK) having a sequence set forth in SEQ ID NOs: 7, 11, or 12.

The Office rejected claims 1, 3-9, 11-16, 30, and 32-38 under 35 U.S.C. § 102(e) for assertedly being anticipated by U.S. Patent No. 6,822,138 ("Schreiber").

B. THE REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN.

The sole outstanding rejection of the claims is a rejection of claims 1, 3-9, 11-16, 30, and 32-38 under 35 U.S.C. § 102(e) for assertedly being anticipated by Schreiber. The rejection is respectfully traversed for the reasons set forth below.

Schreiber anticipates the pending claims only if the reference teaches each and every element of the pending claims. See, e.g., *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631 (Fed. Cir. 1987). Claims 1, 3-9, 11-16, 30 and 32-38 are directed to a preparation or pharmaceutical composition comprising one or more polyclonal, monoclonal, chimeric, humanized, human or anti-anti-idiotype antibodies and/or fragments thereof capable of specifically binding the amino acid sequence set forth in SEQ ID NOs: 7, 11, or 12. The referenced amino acid sequences are subregions or fragments of the NIK protein. Schreiber discloses a genus of antibodies that bind NIK, and does not teach each and every feature of the instant antibody or antibody fragment that selectively binds an amino acid sequence as recited in the pending claims. Disclosure of a genus does not necessarily anticipate a claimed species. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category"). Indeed, the reference does not teach or suggest the specific portion of NIK to which the claimed antibody

binds, nor does the reference teach a subset of antibodies that specifically bind the recited NIK fragments.

The Office reiterated that "given that polyclonal antibodies are known to bind multiple epitopes on one antigen, the prior art polyclonal antibody raised against NIK would necessarily bind to the epitopes comprising the amino acid sequences of SEQ ID NO: 7, 11 or 12." See Office Action, p. 3. The Office then stated that "[w]hile it is acknowledged that polyclonal antibodies do not inherently bind all epitopes, Applicant has not provided objective evidence to show that a polyclonal antibody taught by Schreiber would not bind epitopes of SEQ ID NO: 7, 11, or 12." Office Action, p. 4. Reconciling these statements, the Office appears to be asserting that while the polyclonal antibodies don't inherently bind all epitopes, when it comes to anti-NIK polyclonal antibodies, they inherently bind the claim-recited sequences. Under the law, however, to inherently anticipate a claim, the undisclosed subject matter must necessarily be present. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Without such evidence or reasoning, the Office cannot require an applicant to prove that the prior art does not possess the claimed characteristic. M.P.E.P. § 2112(IV); See also *Ex parte Jurg Zimmerman* 2003 WL 25277881, *4 (Bd. Pat. App. & Interf. 2003), quoting *Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Interf. 1986). Applicants agree wit the Office that polyclonal antibodies do not necessarily bind all epitopes and, thus, Schreiber's apparent disclosure of polyclonal anti-NIK antibodies is not a disclosure that an anti-NIK antibody necessarily binds the claim-recited NIK sequences. Applicants disagree with the Office's contrary statement that prior art polyclonal anti-NIK antibodies would necessarily bind the claim-recited sequences. The Office has the burden of providing evidence or reasoning to support its position that, while polyclonal antibodies in general don't necessarily, or inherently, bind all epitopes, polyclonal anti-NIK antibodies do necessarily, or inherently, bind the claim-recited epitopes. The Office has not satisfied this burden, and there is no basis for expecting the claim-recited epitopes to behave so anomalously. Thus, Applicants submit that the Office has not, and cannot, meet

the burden of establishing a *prima facie* basis for rejecting any claims as anticipated in view of Schreiber. Accordingly, the rejection should be withdrawn. Moreover, in the absence of a *prima facie* showing of anticipation, Applicants have no burden to produce any evidence. M.P.E.P. § 2112(V). In this case, the Office has admitted that polyclonal antibodies do not inherently bind all epitopes. Thus, it is improper to place the burden on the applicant to prove that Schreiber's antibody does not bind SEQ ID NOs: 7, 11, or 12.

Applicants have shown that features of the claimed antibodies are not necessarily, i.e., inherently, found in the genus of anti-NIK antibodies of Schreiber. The reference fails to explicitly or inherently disclose the particular anti-NIK antibodies of the pending claims. Therefore, the rejection of claims 1, 3-9, 11-16 and 32-38 under 35 U.S.C. § 102(e) over Schreiber has been overcome and should be withdrawn.

C. CONCLUSION

Applicants submit that the pending application is in condition for allowance. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions concerning this submission that might be efficiently resolved in that manner.

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Respectfully submitted,

By _____

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